

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	C.A. No. 21-1015 (JLH)
SAREPTA THERAPEUTICS, INC., Defendant.)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
v.)	
NIPPON SHINYAKU CO., LTD. And NS PHARMA, INC., Plaintiff/Counter Defendants.)	

**NS’S RESPONSE TO *DAUBERT* MOTION NO. 4 TO EXCLUDE
DR. LUEDTKE’S DOCTRINE OF EQUIVALENTS OPINIONS AND TESTIMONY**

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Dated: January 12, 2024

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I INTRODUCTION

Defendant-Counterclaim Plaintiffs Sarepta Therapeutics, Inc. and the University of Western Australia’s (together, “Sarepta”) motion to exclude the opinions and testimony of Nippon Shinyaku Co. Ltd.’s (“NS”) expert Dr. Nathan W. Luedtke regarding infringement of U.S. Patent No. 10,683,322 (the “’322 Patent”) under the doctrine of equivalents should be denied. D.I. 395. Sarepta’s motion is based on demonstrably incorrect interpretations of Dr. Luedtke’s opinions and analysis. Specifically, Sarepta contends that (i) Dr. Luedtke’s analysis vitiates a claim element [REDACTED] and (ii) conducts a hypothetical claim analysis instead of comparing the accused process to each element of the asserted claims. Sarepta is wrong—it simply ignores entire sections of Dr. Luedtke’s expert reports containing the exact analysis that Sarepta says is both required and missing. Contrary to Sarepta’s assertions, Dr. Luedtke conducted the proper element-by-element analysis, has specifically identified the equivalent of [REDACTED] in the accused product, and has opined that the accused process infringes under the doctrine of equivalents as documented in his expert reports. Because Sarepta’s only arguments for excluding Dr. Luedtke are factually baseless, its motion to exclude Dr. Luedtke’s opinions should be denied.

II ARGUMENT

A. Dr. Luedtke Conducted a Proper Hypothetical Claim Analysis

Much of Sarepta’s argument focuses on Dr. Luedtke’s hypothetical claim analysis. D.I. 395 at 15-20. However, as Dr. Luedtke has explained in detail, his hypothetical claim analysis was conducted for proper reasons. Specifically, Dr. Luedtke has used the hypothetical claim analysis to explain how a POSA would understand the various steps involved in the doctrine of equivalents (“DOE”) analysis. *See, e.g.*, NS Ex. 52, Luedtke Opening ¶¶ 131-182. Specifically, [REDACTED] of the ’322 Patent include starting materials, a “net chemical transformation” and the ending compound. NS Ex. 53, Luedtke Reply ¶¶ 29-34. Dr. Luedtke uses the hypothetical claim analysis to

explain how a POSA would evaluate these net chemical transformations. NS Ex. 52, Luedtke Opening ¶¶ 131-182.

Further, as Dr. Luedtke has explained, “a hypothetical claim analysis is necessary where, as here, the alleged infringer has raised the possibility that the application of the doctrine of equivalents would ensnare the prior art.” NS Ex. 53, Luedtke Reply ¶ 9. Dr. Luedtke has “provided opinions and analysis showing that each of [the] proposed hypothetical claims literally encompasses the accused methods for manufacturing golodirsén” as is required in order to evaluate whether the application of DOE ensnares the prior art. *Id.* ¶ 10.

Finally, Dr. Luedtke has explained that he further [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶ 11. In all respects, Dr. Luedtke’s hypothetical claim analysis was both correct and necessary, and is not a basis to exclude Dr. Luedtke’s opinions.

B. Dr. Luedtke’s Analysis Does Not Violate the All Elements Rule

In addition to Dr. Luedtke’s hypothetical analysis, he also conducts analysis under the function-way-result and the insubstantial differences test, as Sarepta itself admits. D.I. 395 at 15. However, Sarepta argues that Dr. Luedtke violates the all elements rule because Dr. Luedtke fails to identify [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 17-18. This is factually incorrect. Dr. Luedtke specifically conducted an analysis showing that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

NS Ex. 52, Luedtke Opening at ¶ 184; *see also id.* ¶¶ 183-192; *id.* ¶ 186 (opining that the accused product [REDACTED];

NS Ex. 53, Luedtke Reply ¶ 12 [REDACTED]

[REDACTED]

[REDACTED] Dr. Luedtke's analysis specifically identifies the equivalent of [REDACTED] in the accused process. *See* NS Ex. 52, Luedtke Opening ¶ 184, 187; NS Ex. 53, Luedtke Reply n. 1.

Contrary to Sarepta's arguments, Dr. Luedtke compared each element of the claimed process to the accused process and found that the elements were insubstantially different. NS Ex. 52, Luedtke Opening ¶¶ 183-192; NS Ex. 53, Luedtke Reply ¶¶ 12-13. Since Dr. Luedtke's opinions do not violate the all elements rule, his opinions should not be excluded.

III CONCLUSION

The Court should deny Sarepta's motion to preclude Dr. Luedtke's opinions.

Dated: January 12, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Amy Dudash, certify that on January 12, 2024, I caused a copy of the foregoing document which was filed under seal, to be served via electronic mail on the following counsel of record:

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